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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/457,228	12/08/1999	GARY K. MICHELSON	101.0084-00000	7453

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EXAMINER

SNOW, BRUCE EDWARD

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 04/21/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

N.K

Office Action Summary	Application No.	Applicant(s)
	09/457,228	MICHELSON, GARY K.
	Examiner	Art Unit
	Bruce E Snow	3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 15 August 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-120 and 131-243 is/are pending in the application.
 - 4a) Of the above claim(s) 1-56, 109-113, 131-145, 201 and 202 is/are withdrawn from consideration.
- 5) Claim(s) 203-237 is/are allowed.
- 6) Claim(s) 57-108, 114-120, 146-200 and 238-243 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some *
 - c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>17</u> . | 6) <input type="checkbox"/> Other: _____ |

Response to Arguments

Applicant's arguments filed 5/9/02 and 8/15/02 have been fully considered and are not fully persuasive.

Applicant has elected the spinal implant embodiment shown in figure 16; this embodiment is made of three different types of bone engaging structures. As outlined and described by applicant in the interview, paper No. 13, the three types are elements 422 (highlighted in yellow); 460 (pink); and 470 (green); see the attachment to said interview summary showing applicant's highlights. Applicant further indicated that claim 57 (and it's depending claims) is directed to bone engaging structure 422; claim 146 (and it's depending claims) is directed to structure 460; and claim 175 (and it's depending claims) is directed to 470. It is the Examiner's position that any one of the structure types as claimed is not patentable by itself or in combination with one other type. However, all three in combination is inventive; therefore, new claim 203 and its depending claims are allowed.

During the interview, applicant expressed the desire to assist in anyway possible due to the numerous claims and suggested to remain focused on the independent claims. The Examiner appreciates this gesture. The Examiner, therefore, will address the independent claims only with the dependent claims in stand/fall together format.

First, claim 146 claims element 460. Element 460 is identical to those shown by Willert et al (4,944,763). Emphasis added. Claim 460 is at least rejected in a combination rejection with the elements of Willert et al substituted or added to the spinal implant of Paul et al. This combination is obvious to one having ordinary skill in the art

including possibly applicant's representative describing the uses of their device, "the surface configuration is applicable to any interbody spinal fusion implants including *but not limited to an artificial disc..*" See Supplement Amendment, paper No. 16, page 4, second paragraph. It is the Examiner's position that the elements of Willert et al would be obvious to use on any orthopedic implant.

Second, claim 175 claims element 470. Claim 175 is rejection at least by the combination rejection utilizing the elements 30 of Suddably having a multiple sided conical-like configuration replacing or added to the bone engaging structures of Paul et al. Elements 30 of Suddably clearly meet the limitations of claim 175.

Finally, claim 57 claims element 422. It is the Examiner's interpretation that the longitudinal axis is the longest axis measured between opposite corners of the implant fulfilling all applicant's argument. Additionally, Tsitsopoulos (WO 98/58604) has been included to the combination rejection which clearly meets the limitations of claim 57.

The combination rejection is not verbose but believed accurate and necessary when dealing with numerous claims with varying combinations. Applicant's combinations of the three different bone engaging structures include wide ranges, varying angles, etc. which are impossible to keep straight. Applicant has tried to amend the specification to support wide variations like "facet 476 may also be approximately perpendicular to at least one of the upper and lower surface" which is mechanically impossible. Applicant is trying to describe the non-elected embodiment shown in figure 20 but as described does not make sense. Applicant should have further described the elected embodiment with a longitudinal or transversal cut to include the embodiment of

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figure 20. The Examiner is not going to withdraw any additional claims, but makes it applicant's duty to make sure all configurations described in all the dependent claims make mechanical sense.

Specification

The amendment filed 8/15/02 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. All added material was not supported by the original disclosure and should be deleted. See Example above. Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 102

I. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Claim Rejections - 35 USC § 103

II. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Patentability shall not be negated by the manner in which the invention was made.

III. Claims 57-108, 114-120, 146-200, and 238-243 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Paul et al (6,258,125) in view of Suddaby (6174334), Willert et al (4,944,763), Nishijima et al (5,899,941) or Tsitsopoulos (WO 98/58604).

Paul et al teaches a spinal implant comprising bone engaging structures that can be pyramid-shaped as shown in figures 4-7, for example. The upper and lower surfaces of the implant are curved in a side view and are angled relative to each other. Due to said curved upper and lower surfaces, some of the engaging structures have a forward facing facet that is longer than a rearward facing facet; and said rearward facing facet has a steeper slope. Note that different rows and/or columns, etc., can be considered different plurality of engaging structures. Further note, figures 9-11 which show the structures can be angled; it is the Examiner's position that figures 9 and 10A show an angled pyramid-shape.

In the alternative (combination rejection under 35 U.S.C. 103(a)), Paul et al teaches engaging structure as described above, it would be obvious to one having ordinary skill in the art to substitute all or some of the engaging structures of Paul et al with any known structures including those taught by Suddaby (6174334), Willert et al (4,944,763), Nishijima et al (5,899,941) or Tsitsopoulos (WO 98/58604) for their desired characteristics such as directional anchoring or ease of manufacturing, etc.

Many of applicant's dependent claims claim a wide range of possibilities, for example, an angle can be less than 90 degrees, equal to 90 degrees, greater than 90 degrees, lacking any criticality in the specification, the use these varying ranges in lieu

of those used in the references solves no stated problem and would have been an obvious matter of design choice within the skill of the art.

Additionally, many of the dependent claims claim elements/materials/shapes/etc. which are all well known in the art would have been obvious to one having ordinary skill.

Allowable Subject Matter

Claims 203-237 are allowed. Again, it is applicant's responsibility to check the feasibility of all claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

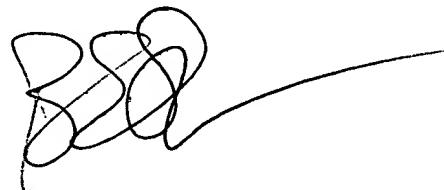
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E Snow whose telephone number is (703) 308-3255. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (703)308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

bes
March 31, 2003



BRUCE SNOW
PRIMARY EXAMINER